Date of Approval: August 19, 2003

FREEDOM OF INFORMATION SUMMARY

ANADA 200-357

This approval provides for the combined use of two approved Type A Medicated Articles (Pennchlor™-chlortetracycline, Bio-Cox® -salinomycin) for use in the manufacture of Type C Medicated Feeds for broiler chickens.

Sponsored by:

Pennfield Oil Company
Omaha, Nebraska 68144

I. GENERAL INFORMATION:

a. File Number**:**	ANADA 200-357
b. Generic Sponsor:	PennField Oil Company 14040 Industrial Road Omaha, Nebraska 68144 Drug Labeler Code: 053389
c. Established Names:	Chlortetracycline Salinomycin sodium
d. Proprietary Names:	Pennchlor™ (Pennfield Oil Co.) Bio-Cox® (Alpharma, Inc)
e. Dosage Form:	Type A Medicated Articles
f. How Supplied:	Chlortetracycline HCl: 50-lb bags Salinomycin sodium: 50-lb bags
g. How Dispensed:	OTC
h. Amount of Active Ingredient(s):	Chlortetracycline- 50 to 100 g/lb in Type A Medicated Articles Salinomycin sodium- 40 and 60 g/lb in Type A Medicated Articles
i. Route of Administration:	These drugs are administered orally by adding the Type A Medicated Articles to complete broiler chicken feed (TypeC Medicated Feed)
j. Species/class:	Broiler Chickens

k. Recommended Dosage: Chlortetracycline, 500 grams per ton (.055%)
Salinomycin Sodium, 40 to 60 grams per ton (.0044-.0066%)

l. Pharmacological Category: Antibacterial

m. Indications for use: For the prevention of coccidiosis in broiler chickens caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina, E. maxima*, *E. brunetti*, and *E. mivati*, and as an aid in the reduction of mortality due to *E. coli* infections susceptible to such treatment.

n. Pioneer Products:

Aureomycin®
Chlortetracycline
NADA 48-761
Alpharma, Inc.

Bio-Cox®
Salinomycin sodium
NADA 128-686
Alpharma, Inc.

Aureomycin®-Bio-Cox®
Chlortetracycline/Salinomycin
NADA 140-859
Alpharma, Inc.

Pennchlor™
Chlortetracycline
NADA 138-935
Pennfield Oil Company

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

Pennchlor™ and Aureomycin® were both found to comply with the results of NAS/NRC/ DESI evaluation for effectiveness as published in the FEDERAL REGISTER (61 FR 35949-35958; July 9, 1996). These products approved under the DESI process were found to be equivalent at the codified level 21 CFR § 558.128(e)(1)(iv) of 500 g/ton for chickens (61 FR 35949-35958; July 9, 1996).

The Center's fourth generic policy letter dated November 2, 1989, as published in the FEDERAL REGISTER on January 30, 1990 (55 FR 3107), states that the approval of a new generic Type A Medicated Article entitles the sponsor to approval of all the feed combinations for which the pioneer is approved. Bioequivalence and tissue residue studies are not required for approval of the feed use combinations.

Chlortetracycline (Pennchlor™-Pennfield) is codified under 21 CFR § 558.128(e)(1). Chlortetracycline (Aureomycin®-Alpharma) is codified under 21 CFR § 558.128(e)(1). Salinomycin sodium is codified under 21 CFR § 558.550. The combination is codified under 21 CFR § 558.550(d)(1)(xvi) and the NADA 140-859 was approved on August 13, 1989.

3. HUMAN SAFETY:

· Tolerances for Residues:

The tolerances established for the pioneer product apply to the generic product.

Tolerances for the sum of residues of tetracycline, including chlortetracycline in tissues of chickens, are as follows: (a) 2 parts per million (ppm) in muscle; (b) 6 ppm in liver; (c) 12 ppm in fat and kidneys (21 CFR § 556.150). The acceptable daily intake for residues of chlortetracycline is 25 micrograms per kilogram of body weight per day.

Under NADA 128-686 a tolerance for salinomycin was not required because residue levels in all three broiler tissues (muscle, liver, and skin/fat) were significantly below the established safe concentration. The acceptable daily intake (ADI) for total residues of salinomycin is 0.005 milligram per kilogram of body weight per day (21 CFR § 556.592).

· Withdrawal Times:

Based on the limitation in 21 CFR § 558.550(d)(1)(xvi), a 24 hour withdrawal time is required for the combination of chlortetracycline and salinomycin.

· Regulatory Methods for Residues:

The regulatory analytical method for the determination of residue of chlortetracycline is a microbiological test using *Bacillus cereus* var. *mycoides* (ATCC 11778). The method is found in *Antibiotic Residues in Milk, Dairy Products, and Animal Tissues: Methods, Reports and Protocols*, Revised October, 1968, Reprinted December 1974, National Center for Antibiotic and Insulin Analysis, FDA, Washington, DC 20204.

4. AGENCY CONCLUSIONS:

This ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512 (n) of the act and demonstrates that the combination of chlortetracycline and salinomycin sodium when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile generic labeling and currently approved pioneer labeling are attached below:

Type C Medicated Feed (Blue Bird) – Generic Labeling for ANADA 200-357

Type C Medicated Feed (Blue Bird) – Pioneer Labeling NADA 140-859